K121128

JUN - 6 2012

510(k) SUMMARY AS REQUIRED BY 21 CR § 807.87(h)

Submitter's Name and Address:	Irvine Scientific Sales Co., Inc. 2511 Daimler Street Santa Ana, CA 92705-5588
Manufacturing Site:	2511 Daimler Street Santa Ana, CA 92705-5588
Contact Person:	Jayme Yamaguchi-Owens Regulatory Affairs Manager Irvine Scientific 2511 Daimler Street Santa Ana, CA 92705-5588 Tel: 949-261-7800 ext 254 Fax: 949-261-6522 Email: jfy@irvinesci.com
Date of Application:	April 9, 2012
Establishment Registration Number:	2022379
510(k):	K121128
Trade or Proprietary Name:	Multipurpose Handling Medium™ (MHM™)
Device Name:	Handling Medium
Device Classification:	Reproductive Media and Supplements
Device Regulation:	21 CFR § 884.6180
Device Classification:	Class II (Special Controls)
Product Code:	85 MQL
Predicate Device:	Modified HTF (mHTF), K983586 G-MOPS™/G-MOPS™ PLUS, K081115
Performance Standards:	None established

Purpose:

Purpose of this application is to obtain 510(k) marketing clearance for the Multipurpose Handling Medium™ (MHM™).

Indication for Use:

Multipurpose Handling Medium™ (MHM™) is intended for use in assisted reproductive procedures which involve the manipulation of gametes or embryos. Specifically, Multipurpose Handling Medium™ (MHM™) is indicated for use as an oocyte retrieval medium during ovarian follicle aspiration procedures (not for flushing ovarian follicles), washing sperm prior to IVF and ICSI fertilization procedures, and for transport of the embryo to the uterus during embryo transfer procedures.

Description of the Device:

The Multipurpose Handling Medium™ (MHM™) is based upon the mHTF (K983586) formulation. The formula for the Multipurpose Handling Medium™ (MHM™) is based upon the composition of modified HTF, K983586. The medium uses a buffering system composed of HEPES (N-2-Hydroxyethylpiperazine-N^1 -2 – ethanesulfonic acid), MOPS (3 Morpholinopropane – 1- sulfonic acid) and Sodium Bicarbonate. This buffering system provides pH maintenance over the physiologic range and does not require the use of a CO_2 Incubator. The product also contains 10 μg/mL gentamicin.

Multipurpose Handling Medium™ (MHM™) has utility as an oocyte retrieval medium, in procedures that aspirate oocytes from the patient's ovarian follicles. Multipurpose Handling Medium™ (MHM™) is used only in the oocyte collection vessel and is not for use in flushing oocytes from ovarian follicles. Once the oocyte has been retrieved, it is placed into a culture dish with an appropriate amount of a culture medium (does not include MHM™), as specified by the user's internal procedures, and fertilization is allowed to occur. Multipurpose Handling Medium™ (MHM™) can also be used to wash sperm in preparation for

fertilization by conventional IVF or ICSI procedures. The fertilized oocyte (zygote) is allowed to grow in the culture dish, supported by a culture medium (does not include MHM™), as specified by the user's internal procedures, and an appropriate protein supplement, in a carbon dioxide incubator at 37°C until the desired stage of development is achieved. The embryo is removed from the culture dish, placed into an appropriate amount of Multipurpose Handling Medium™ (MHM™) for transfer into the uterus.

Multipurpose Handling Medium™ (MHM™) is supplied as a ready to use liquid, in 100 and 500 mL bottles.

Technological Characteristics:

Multipurpose Handling Medium™ (MHM™) can be used as an oocyte collection medium during in procedures that aspirate oocytes from the patient's ovarian follicles. Multipurpose Handling Medium™ (MHM™) is used only in the oocyte collection vessel and is not for use in flushing oocytes from ovarian follicles. Once the oocyte has been retrieved, it is placed into a culture dish with an appropriate amount of a culture medium, as specified by the user's internal procedures, and fertilized. After fertilization, the embryo is allowed to develop in a culture medium, as specified by the user's internal procedures, until an appropriate developmental stage is reached. After incubation of the embryo, to the appropriate developmental stage, the embryo is removed from the incubation dish and placed into a suitable amount of Multipurpose Handling Medium™ (MHM™) for transport and transfer into the patient. Multipurpose Handling Medium™ (MHM™) can be used for washing sperm from its surrounding seminal fluid. Once semen has liquefied it is placed into a conical tube with a volume of room temperature Handling Medium™ (MHM™) and centrifuged to separate the sperm from the seminal fluid prior to IVF and ICSI fertilization procedures. Multipurpose Handling Medium™ (MHM™) is therefore intended for use as an oocyte retrieval medium, as a transport and storage medium and as a sperm-washing medium.

Multipurpose Handling Medium™ (MHM™) is similar to mHTF (K983586) it is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos. mHTF is also intended for use as a sperm-processing medium in washing procedures, as an oocyte retrieval medium, for transport of the embryo, and as a support medium for transfer of the embryo. mHTF is intended to simulate the substances found in the human, female reproductive system.

Multipurpose Handling Medium™ (MHM™) is similar to G-MOPS™ and G-MOPS™ PLUS (K081115) in that is intended for oocyte collection and for handling and manipulating oocytes and embryos in ambient atmosphere.

Performance Data:

Multipurpose Handling Medium™ is assayed by one (1) -cell mouse embryo assay (MEA) prior to release to the market. This assay assures that the product is both functional for its intended use and no embryo-toxic components are present in the formulation.

Multipurpose Handling Medium™ (MHM™) is also assayed human sperm survival assay was also performed prior to release to the market. This assay also assures that the product functions in accordance with its intended use with regards to sperm wash procedure and that no sperm-toxic components are present in the formulation.

Nonclinical Tests:

One (1) -cell MEA was performed on the Multipurpose Handling Medium™ (MHM™) as part of the design validation. Testing was performed at three (3) different test facilities after 2 hours exposure to the Multipurpose Handling Medium™ (MHM™).

In addition, human sperm survival assay was also performed on donor specimens that were initially processed by gradient separation and resulting motile specimens were equally divided and the average % motility after 24 hours

at 37°C in ambient air was determined. The field evaluations demonstrate that the Multipurpose Handling Medium™ (MHM™) was "equal" to the proven control medium of mHTF (K983586).

Additional Information:

Endotoxin, pH, osmolality, mouse embryo assay, human sperm survival assay and sterility tests will be performed as a condition of release for Multipurpose Handling Medium™ (MHM™). Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling.

Conclusion:

The conclusion from the performance testing as well as the nonclinical and clinical data demonstrates that the Multipurpose Handling Medium™ (MHM™) is suitable for its intended use, and meets the criteria in the comparison to predicate devices in which substantial equivalence has been demonstrated and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket Number 97N-0335.

A comparison of the Predicate Device Intended Use, Product Formula and Product Specifications are summarized below that demonstrate substantial equivalence.

Table 1: Predicate Intended Use Comparison

Product Name	K#	Retrieval / Collection	Culture	Transfer	Ambient
Modified HTF (mHTF) Medium – HEPES	K983586	+	+	+	+
G-MOPS™/G-MOPS™ PLUS	K081115	+	+	+	+

Table 2: Product Formulation Comparison

Raw Materials	Multipurpose Handling Medium™, Catalog #90163	Modified HTF (K983586)	G-MOPS™ (K081115)	G-MOPS™ PLUS (K081115)
WFI Quality Water	+	+	+	+
Phenol Red, Na Salt	+	+	–	–
Sodium Bicarbonate	+	+	+	+
Sodium Chloride	+	+	+	+
Potassium Chloride	+	+	+	+
Dextrose	+	+	+	+
Magnesium Sulfate	+	+	+	+
Potassium Phosphate	+	+	–	–
Pyruvic Acid, sodium salt	+	+	–	–
DL-Lactic Acid, sodium	+	+	+	+
Glycine	+	–	+	+
Taurine	+	–	+	+
Calcium Chloride, anhydrous	+	+	+	+
HEPES ½ sodium salt [4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid, ½ sodium salt]	+	+	–	–
HEPES Sodium salt [4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid, sodium salt]	–	+	–	–
MOPS, sodium salt	+	–	+	+
Gentamicin Sulfate	+	+	+	+
Alanine	+	+	+	+
Alanyl-glutamine	+	+	+	+
Asparagine	+	+	+	+
Aspartate	+	+	+	+

Raw Materials	Multipurpose Handling Medium™, Catalog #90163	Modified HTF (K983586)	G-MOPS™ (K081115)	G-MOPS™ PLUS (K081115)
Glutamate	+	+	+	+
Glycine	+	+	+	+
Lipoic Acid	+	+	+	+
Methionine	+	+	+	+
Proline	+	+	+	+
Serine	+	+	+	+
Sodium citrate	+	+	+	+
Sodium Hydrogen Phosphate	+	+	+	+
Sodium Pyruvate	+	+	+	+
Human serum albumin	–[1]	+	+	+

Table 3: Predicate Device Product Specification Comparison

Specification	Multipurpose Handling Medium™	Modified HTF (K983586)	G-MOPS™ / G-MOPS™ PLUS (K081115)
pH	7.25 – 7.54	7.25 – 7.54	Unknown
Osmolality	275 – 295 Osm/KgH_2O	272 – 288 Osm/KgH_2O	Unknown
Sterility	Pass	Pass	Pass
Endotoxin	≤ 0.25 EU/mL	≤ 0.25 EU/mL	≤ 0.25 EU/mL
MEA	≥ 80%	≥ 70%	≥ 80%
HSSA	≥ 70% of original motility at 24 hours	NT[2]	NT

[1] Protein supplementation is to be performed prior to use
[2] NT – Not Tested

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Jayme Yamaguchi-Owens
Regulatory Affairs Manager
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SANTA ANA CA 92705

JUN - 6 2012

Re: K121128
Trade/Device Name: Multipurpose Handling Medium™ (MHM™)
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: April 9, 2012
Received: April 13, 2012

Dear Ms. Yamaguchi-Owens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K121128

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Indications for Use:

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Prescription Use ___X____ (Part 21 CFR § 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR § 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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Benjamin R. Fisher 06 June 2012
(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
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